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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,038	01/24/2000	Taro Takahashi	US000034	6624

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1625

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/490,038	TAKAHASHI ET AL.
<b>Examiner</b>	<b>Art Unit</b>	
Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 05 March 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-7 and 11 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7 and 11 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/2003 has been entered.

**The Status of Claims:**

Claims 1-7 and 11 are pending.

Claims 1-7 and 11 have been rejected.

***Claim Rejections - 35 USC § 112***

Claims 1 , 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for carboxylic acids, such as acetic acid, lactic acid, tartaric acid, citric acid, succinic acid, fumaric acid, does not reasonably provide enablement for all the carboxylic acid known in the field of chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the carboxylic acids unrelated to the invention

commensurate in scope with these claims. Furthermore, there are "foreman factors or Wands factors" regarding unpredictability because a carboxylic acid includes any carboxylic acid with any heterocyclic group, any aromatic group, any alicyclic group, and a diverse scope of acyclic groups. In addition, it does not exclude any bi-functional acid such as a variety of amino acids. Moreover, as the molecular weight varies substantially, therefore, not all acids are liquid and also more than routine experimentation is involved. See In re Armbruster 185 USPQ 204 (CCPA 1985) and Angstadt et al., 190 USPQ 152 (CCPA 1990). Therefore, an appropriate correction is required.

The specification, while being enabling for amino acids and amino acid condensates, such as protein, zein, gluten, casein, whey protein, gelatins, egg white albumin and etc., does not reasonably provide enablement for all the amino acids and amino acid condensates known in the field of the food chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the amino acids and amino acid condensates unrelated to the invention commensurate in scope with these claims. Therefore, an appropriate correction is required.

The specification, while being enabling for a fatty acid, such as caprylic acid, capric acid, lauric acid, palmitic acid, stearic acid , oleic acid , linoleic acid ,and etc., does not reasonably provide enablement for all the amino acids and amino acid condensates known in the field of the organic chemistry. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the fatty acids unrelated to the invention commensurate in scope with these claims. Therefore, an appropriate correction is required.

Claims 1 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the specification, there is found no phrase, such as "a reduction catalyst", but there is a term "catalysts." As a consequence, the word "reduction" is not enabled in such a way that one skilled in the art can accept the term in the claim language. Therefore, an appropriate correction is required.

Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A term "a high-pressure" is written. However, it is vague and indefinite. The high pressure may be interpreted in many ways: for example, the pressure at least above the atmospheric pressure or the pressure far above the atmospheric pressure. Therefore, an appropriate pressure range is required.

***Claim Rejections - 35 USC § 102***

2113 Product-by-Process Claims

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATION OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 77 F.2d 695,698,227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive prereacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Madsen et al (U.S. 5,189,016).

Madsen et al discloses a glutaminyl-glycine dipeptide having a N-terminal amino acid as shown in the specification (see col. 4 , lines 12-25). This is identical with the claim.

***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heins et al (U.S. 4,032,676) in view of Goldberg (Schaum's Beginning Chem., P. 250).

Heins et al teach a method of making N-polyhydroxyalkylamino acids by reacting uronic acids in alcohols, ethers or their mixtures with water in the presence of amino acids at a temperature between 50<sup>0</sup> to 100<sup>0</sup> C.(See col. 3 ,lines 58-65).

However, the instant invention differs from Heins et al in that the heating is carried out at 105<sup>0</sup> or more and at a high-pressure.

Concerning the heating carried out at 105<sup>0</sup> or more, the claimed ranges and prior art do not overlap, but are close enough that one skilled in the art would have expected them to have a similar reaction condition in the absence of unexpected results. Furthermore, the limitation of a process with respect to ranges of pH, time and temperature does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. Temperature is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity of a chemical process.

With respect to the process at a high-pressure, the Heins et al reference is silent. However, the high pressure may be interpreted in many ways: for example, the pressure at least above the atmospheric pressure or the pressure far above the atmospheric pressure. The reference does not specify the limitation of the pressure in the process, which may mean that the reaction takes place at least at the atmospheric pressure. Furthermore, the range of the pressure in the claim is unspecified. Moreover, the limitation of a process with respect to ranges of pH, time and pressure does not impart patentability to a process when such values are those which would be

determined by one of ordinary skill in the art in achieving optimum operation of the process. Pressure is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity of a chemical process. Therefore, it would have been obvious to the skilled artisan in the art to have optimized the pressure limitation in the Heins et al process.

Heins et al does teach the method of making N-polyhydroxyalkylamino acids by reacting ionic acids in alcohols, ethers or their mixtures with water in the presence of amino acids at a temperature between 50<sup>0</sup> to 100<sup>0</sup> C. without any specific range of the reaction pressure, which indicates that the reaction takes place at or near the atmospheric pressure. In addition, it is well-known that the reaction process is generally enhanced by increasing the pressure as shown in the Goldberg (Schaum's Beginning Chem. P. 250). Therefore, it would have been obvious to the skilled artisan in the art to have motivated to increase the pressure in the Heins et al process by a routine experimentation. This is because the skilled artisan in the art would expect to increase the reaction process by raising the pressure .

6. Claims 1 , 3-4, and 6-7 are rejected under under 35 U.S.C. 103(a) as being unpatentable over van Pottelsberghe dela Potterie (U.S. 3,716,380) in view of Goldberg (Schaum's Beginning Chem., P. 250).

van Pottelsberghe dela Potterie discloses a method of making flavoring substances by reacting a protein hydrolysate, palmitic acid, methionine, lactic acid , water, and etc. at a temperature of 100<sup>0</sup> C. (See col. 3 , Example 2).

However, the instant invention differs from van Pottelsberghe dela Potterie in that the process is carried out at a high-pressure.

With respect to the process at a high-pressure, the Heins et al reference is silent. However, the high pressure may be interpreted in many ways: for example, the pressure at least above the atmospheric pressure or the pressure far above the atmospheric pressure. The reference does not specify the limitation of the pressure in the process, which may mean that the reaction takes place at least at the atmospheric pressure. Furthermore, the range of the pressure in the claim is unspecified. Moreover, the limitation of a process with respect to ranges of pH, time and pressure does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. Pressure is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity of a chemical process. Therefore, it would have been obvious to the skilled artisan in the art to have optimized the pressure limitation in the van Pottelsberghe dela Potterie process.

van Pottelsberghe dela Potterie does teach the method of making flavoring substances by reacting a protein hydrolysate, palmitic acid, methionine, lactic acid, water, and etc. at a temperature of 100° C. without any specific range of the reaction pressure, which indicates that the reaction takes place at or near the atmospheric pressure. In addition, it is well-known that the reaction process is generally enhanced by increasing the pressure as shown in the Goldberg (Schaum's Beginning Chem. P. 250). Therefore, it would have been obvious to the skilled artisan in the art to have motivated

Art Unit: 1625

to increase the pressure in the van Pottelsberghe dela Potterie process by a routine experimentation. This is because the skilled artisan in the art would expect to increase the reaction process by raising the pressure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman , can be reached on (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.



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